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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,389	07/01/2003	Thomas Dedenroth Miller	6458.200-US	1532
23650	7590	01/05/2005	EXAMINER	
NOVO NORDISK, INC. PATENT DEPARTMENT 100 COLLEGE ROAD WEST PRINCETON, NJ 08540			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 01/05/2005 .

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/611,389

Applicant(s)

Miller et al

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

Figures 1-4 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated and applicant indicated these figures as prior art in the Brief Description of the Drawings. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.121(d)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the scale and scale indications must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

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should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Specifically, the present abstract contains the legal phraseology of "comprising" and "means".

Claim Objections

Claims 1-2 are objected to because of the following informalities:

Claim 1 lines 9 and 12 recite “operational coupled”. This is grammatically incorrect and should be changed to –operationally coupled--.

Claim 2 line 2 recites “which curve track”. It seems that a word is missing or misused and therefore the claim language doesn’t read correctly. It is suggested that –wherein the curved track—may be more grammatically correct.

Claim 2 line 2-3 recites “a non-rotatable clicker element”. Claim 1 already set forth “a non-rotatable clicker element” in line 19. Since the specification and drawings only teach one non-rotatable clicker element it is assumed this is a typo. This should be amended to read –the non-rotatable clicker element—to refer back to the clicker element of claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,5,7-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Balkwill (USPN 5,279,585). In general, Balkwill teaches an injection device having a housing (20) with a cartridge (46) containing medication sufficient for a number of doses. The doses are injected by advancing a piston rod (26) forward inside the cartridge. See 4:54-68.

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Regarding claim 1, Balkwill teaches a dose setting and injection mechanism (See figures 5a and 5b including among other elements 22, 36 and 42 which are involved in setting and injecting a dose) comprising an incremental feedback mechanism (clicks of units counter ring 36), a rotatable dose setting member (12) operationally coupled to the dose setting and injection mechanism for setting up a dose to be injected (see 5:24-31), and an injection button (24) operationally coupled to the dose setting and injecting mechanism (see 5:35-39) and by which the dose setting and injection mechanism can be activated for advancing the piston rod forward in order to press out the set dose through a conduit connected to the cartridge (see 4:64-66). The device also has additional clicking means (clicks of the tens counter ring 38) which is provided between the rotatable dose setting member (12) and a non-rotatable clicker element (ridge 42d of zero detection clip 42 which is not disclosed as rotating), the clicking means provides incremental clicks corresponding to a dose volume (10 units). See 6:4-18.

Additionally, it is assumed that applicant is invoking 112 6th paragraph means plus function interpretation regarding “clicking means”. Therefore, “clicking means” has been reviewed and interpreted in the above rejection as means plus function language.

Regarding claims 2, 5, 7-8 and 10, the clicking means comprises a curved track (38a see figures 5b and 11) provided as a part of the rotatable dose setting member (in that track 38a is rotated when the dose setting member 12 is operated; see 5:24-26 and 6:8-11) wherein the curved track engages the non-rotatable clicker element (ridge 42d of zero detection clip 42) provided on or as a part of the injection device. See 6:11-17. The clicker element is a protrusion (42d) provided on the dose setting and injection mechanism. See figure 10. The curved track

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(38a see figures 5b and 11) is provided with a number of spaced indentations and there are 5-60 of these indentations equally spaced. Figure 5b shows the indentations equally spaced and 59 units can be set which means that at least five indentations in the tens counter ring must be present. See 5:60-61. The dose setting member is provided with a scale (the tens counter ring as a part of the dose setting member has a scale on the outside of the ring; see figure 5b) where the scale indications correlate to the indentations (one number for each indentation).

Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Burroughs et al (USPN 5,938,642). In general, Burroughs teaches an injection device having a housing (22) with a cartridge (40) containing medication sufficient for a number of doses. See 1:9-12. The doses are injected by advancing a piston rod (38) forward inside the cartridge. See figure 2.

Regarding claim 1, Burroughs teaches a dose setting and injection mechanism (See figure 2 and including elements 32,36,38) comprising an incremental feedback mechanism (window 25 providing visual feedback), a rotatable dose setting member (34) operationally coupled to the dose setting and injection mechanism (34 and 36 engage during dose setting; see 8:53-54) for setting up a dose to be injected, and an injection button (70) operationally coupled to the dose setting and injecting mechanism (via element 32) and by which the dose setting and injection mechanism can be activated for advancing the piston rod forward in order to press out the set dose through a conduit connected to the cartridge (see 9:26-44). The device also has additional clicking means (8:59-64) which is provided between the rotatable dose setting member (34) and

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a non-rotatable clicker element (170), the clicking means provides incremental clicks corresponding to a dose volume. See 8:49-64.

Additionally, it is assumed that applicant is invoking 112 6th paragraph means plus function interpretation regarding “clicking means”. Therefore, “clicking means” has been reviewed and interpreted in the above rejection as means plus function language.

Regarding claims 2-4 and 6-8, the clicking means comprises a curved track (indentations 150 see figures 7-9) provided as a part of the rotatable dose setting member (34) wherein the curved track engages the non-rotatable clicker element (170) which is a protrusion (176) carried on a flexible arm (172) provided on or as a part of the injection device (housing 26). The rotatable dose setting member is circular with the curved track provided on the periphery (see figures 7-9). The curved track is provided with a number of spaced indentations (150) and there are 5-60 of these indentations equally spaced (see 8:26 and figures 7-9).

Allowable Subject Matter

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to teach, among all the limitations, the combination of, a curved track that engages a non-rotatable clicker element and 5-60 equally spaced indentations where there is an air shot indentation between the first two of the 5-60 equally spaced indentations.

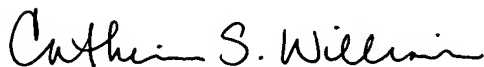
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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846 (as of Nov 4th 571-272-4970). The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams
October 20, 2004